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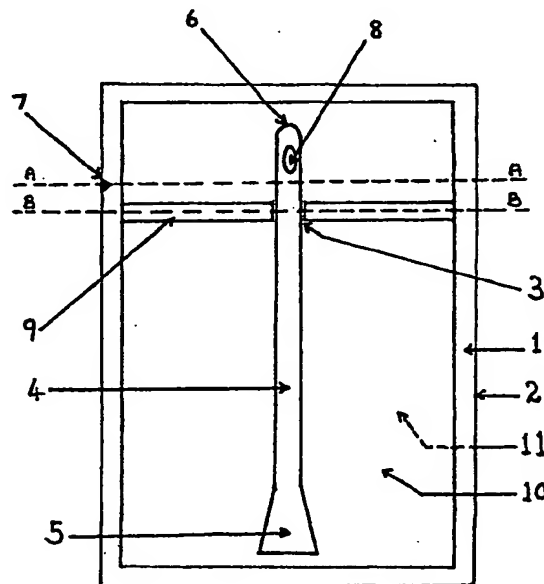
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(54) Catheter and urine collection device assembly

(57) The assembly comprises a catheter 4 having a rounded distal tip 6, drainage aperture 8 and flared proximal portion 5 contained within a flexible container 2 made from plastic film 10, 11. The container has an aperture 3 sufficiently large to permit the tip 6 and shaft of the catheter to pass but small enough to engage the proximal portion 5 of the catheter to form a mechanical seal against leakage of urine. The container may be opened by tearing along line A-A from pre-cut point 7 to expose the tip 6 ready for insertion into the urethra. The assembly may be contained within a second sealed pouch and rendered sterile.

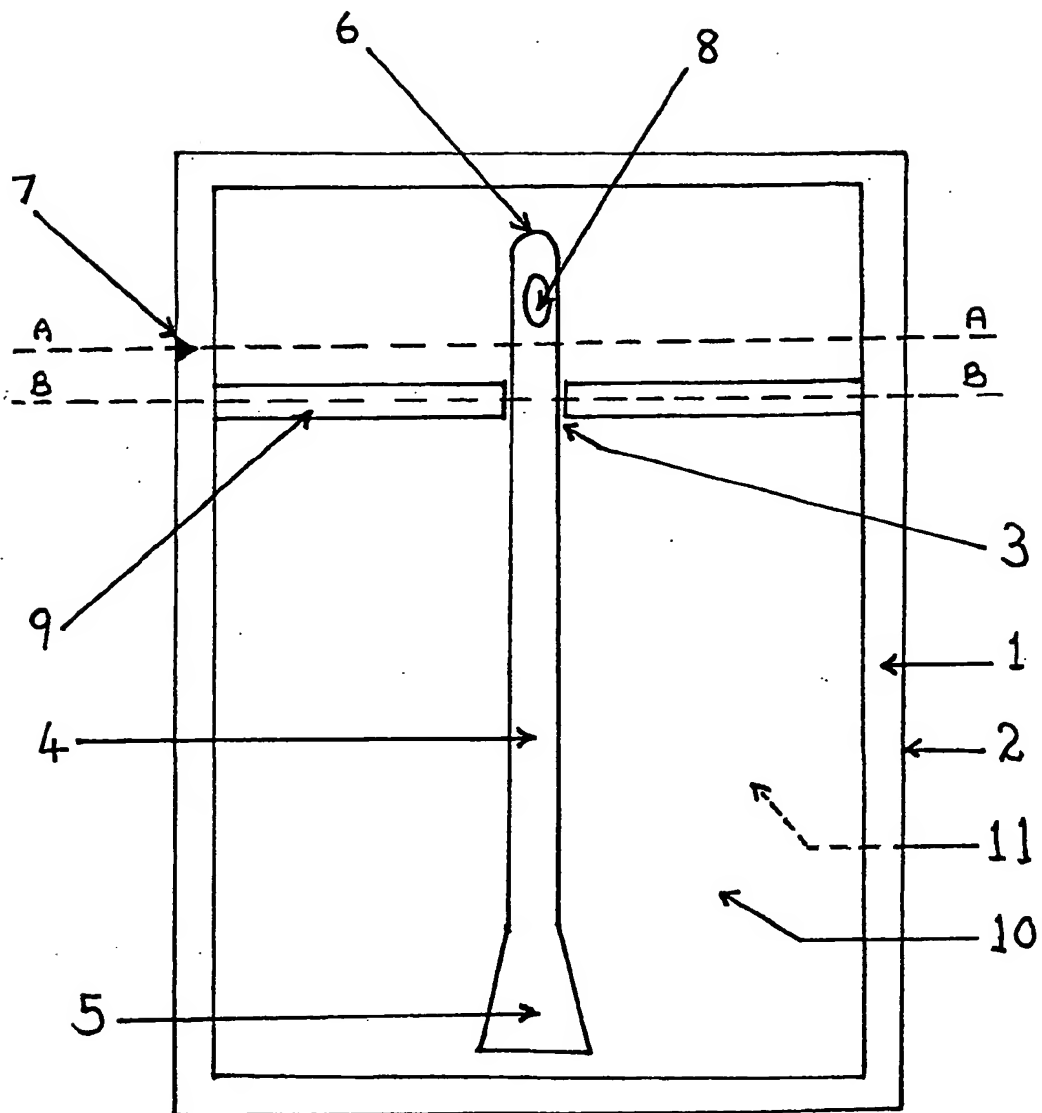
FIGURE 1



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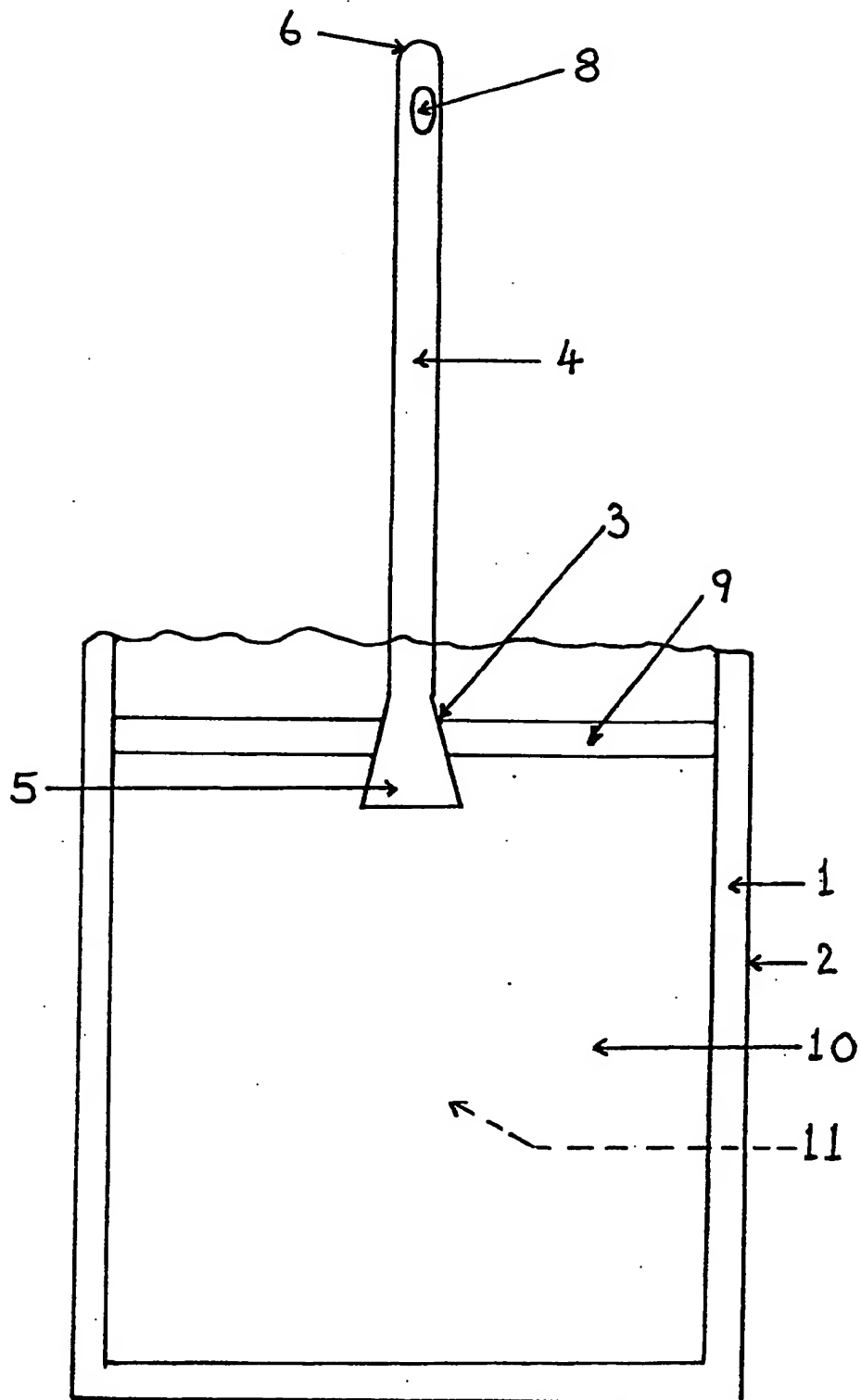
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FIGURE 1/3



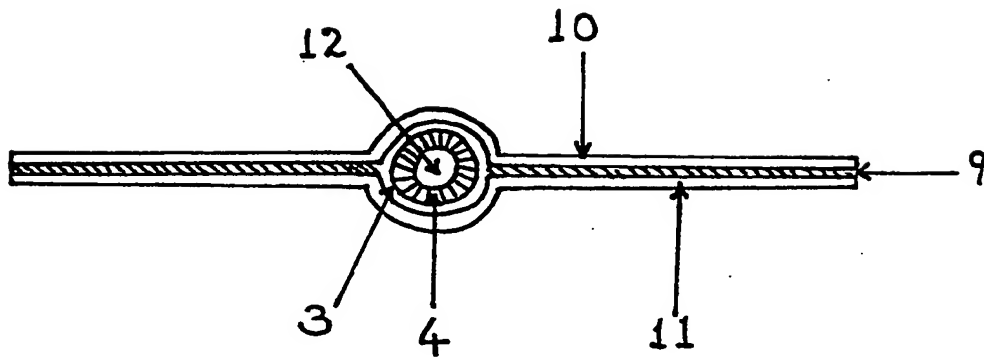
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FIGURE 2/3



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FIGURE 3/3



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A CATHETER AND URINE COLLECTION DEVICE ASSEMBLY

This invention relates to a catheter and fluid collection device assembly for conveniently draining urine from the bladder.

Many victims of paralysis or certain medical conditions are unable to evacuate the bladder voluntarily and these persons must be catheterised from time to time in order to drain their urine.

One of the most common medical procedures is the insertion of a catheter into a patient's urethra and thence into the bladder for the purpose of draining urine therefrom. The procedure may be carried out intermittently for the purpose of periodically emptying the patient's bladder using a simple catheter comprising a flexible, smooth, shaft portion with a central drainage lumen having a distal end comprising a rounded tip portion to avoid traumatising the urethral wall when inserted, at least one drainage aperture piercing the wall of the shaft to the central drainage lumen situated in close proximity to the tip and a proximal end open to allow flow of urine and often fitted with an integral flared portion to permit the attachment of a urine collection bag via a tapered connector, or alternatively the urine may be collected from the catheter into a suitable open receptacle for subsequent disposal.

The procedure of intermittent catheterisation is commonly taught to selected patients in order that they may learn to empty their own bladders on a regular basis every 3-6 hours.

While the procedure may in some instances be carried out under aseptic conditions using a pre-sterilised catheter, it is common practice in many countries for the patient to perform intermittent catheterisation under clean conditions when the catheter may be rinsed out and reused several times. The catheter will usually be stored in a clean container between uses.

Catheters are generally provided separately from the means of collecting and disposing of the urine and it is left to the patient to assemble the necessary additional equipment required to lubricate the catheter, to collect the urine if a urinal or commode is unavailable and to store the catheter if it is to be reused.

The provision of a suitable urine collection bag for each occasion is very costly and the use of an open receptacle is not always convenient as many of these patients are confined to bed or to a wheelchair and cannot easily direct the flow of urine into such a receptacle.

United Kingdom Patent GB 2033231 A discloses a urine collector

and catheter assembly in which the catheter is intended to remain within the collection device for disposal after use and in which the catheter is not intended to form a seal with the collection device during bladder emptying. The disclosed invention is convenient for presenting a catheter in an aseptic condition and for the collection of a urine sample for subsequent analysis but does not address the needs of the patient using a clean technique for the intermittent catheterisation procedure and reusing the catheter several times.

United States Patents similarly illustrative of the state of the art are US 4246909A and US 4204527A.

Patients practising intermittent catheterisation may be forced by circumstances of travel or in the general course of everyday life to empty urine from their bladder away from normal toilet facilities or in public conveniences where the facilities may be unhygienic. In these circumstances the collecting devices disclosed in the above mentioned prior art offer the opportunity for leakage of urine during the procedure since the catheter shaft is a loose fit in the preformed aperture at the top of the collection device. Furthermore the collection device when full of urine cannot readily be transported to a convenient location for emptying without further opportunity for leakage as for example when the patient is travelling by car. Such problems can be distressing for patients and travel tends to be confined to known areas where clean, hygienic toilet facilities are available.

Further, when the clean intermittent catheterisation procedure is completed the patient is required to retain the catheter for future use and must remove the catheter from the collection device with care to avoid splashing urine as the contaminated portion is released. This cannot be accomplished without some difficulty in the case of the above mentioned prior art. A convenient means of storing the used catheter must be to hand and a further means of collecting urine must be available when the patient reuses the catheter 3-6 hours later.

Some patients are advised to apply a lubricious substance to the distal portion of the catheter prior to insertion into the urethra and this can present a further inconvenience when the patient is travelling as the lubricious substance tends to contaminate hands and clothing unless hygienic facilities are available.

According to the present invention there is provided a catheter made from plastics material and having a smooth, substantially parallel, shaft portion with a distal end comprising a rounded, closed tip portion, at least one drainage aperture piercing the wall of the shaft portion to the central drainage lumen of the catheter and a proximal end comprising a gradually flared funnel portion integral with the shaft of the catheter and open to permit the flow of urine, the said catheter is enclosed within an elongated, flexible, plastic container comprising flat, flexible, imperforate plastic sheet material sealed along all

edges save for a preformed aperture at one end of the container sufficiently large to permit the shaft of the catheter to pass through, but small enough to engage with the flared funnel portion at the proximal end of the catheter and form a seal against leakage of urine collected in the container, the said catheter being removably retained within the said aperture until the said aperture is distorted or ruptured.

The flexible plastic container is preferably made from a thermoplastics sheet material such as low density polyethylene in a thickness of between 50 and 100 microns to permit the formation of an aperture which will rupture under an applied load of 5 kilos to release the catheter when pulled and yet will provide for the secure containment of up to 800ml of urine without rupture or leakage.

In one embodiment the said container comprises flexible, flat, imperforate sheet material sealed on all four sides to form a flat, elongate container and includes a further, interrupted seal across the narrow width of the container situated close to one end such that the contents of the container may be rendered sterile and the container may be opened by tearing across the end of the container between the end seal and the nearby interrupted seal to expose the preformed aperture.

A further embodiment of the above invention comprises a flexible container similar in all respects to those previously described but without an end seal on the opposite end to the preformed aperture thus permitting the used catheter to be inserted into the clean, unused flexible container for storage. A suitable clamp such as are commonly in use for sealing ileostomy bags may be used to seal the container rendering it suitable for use in the manner of the original, sealed embodiment.

Yet another embodiment of the invention includes the addition of a lubricious substance within the flexible container during the course of manufacture. The lubricious substance may be a water based jelly and may be enclosed within a plastics material or foil envelope manufactured with a weakened seal to permit the contents to be expelled from the envelope into the flexible container by the application of reasonable pressure on the envelope through the walls of the flexible container, thus lubricating the catheter prior to use without the attendant contamination of hands and clothing which can easily occur if the lubricious substance is applied to the catheter outwith the flexible container.

It is an object of this invention to provide a catheter and urine collection device assembly wherein the catheter may be conveniently manipulated to project from the collection device and at the same time form a leakproof seal against leakage of urine from the collection device.

Another aspect of this invention lies in providing for the release of the catheter from the collection device after use without applying excessive force.

A further object of this invention is to provide for lubrication of the catheter within the collection device prior to use.

Yet another object of this invention is to provide a secondary urine collection device which may be conveniently used to store the catheter after use and to readily permit further use as a urine collection device in the manner already described.

A still further object of this invention is to provide a catheter and urine collection device assembly yielding the foregoing advantages and that is simply and economically constructed.

A specific embodiment of the device will now be described by way of example, with reference to the accompanying drawings in which:

Figure 1 is a plan view of the catheter and urine collection device assembly in which the catheter can be clearly seen through the clear plastic film of the urine collection device in which it is contained.

Figure 2 is a plan view of the catheter and urine collection device assembly after the bag has been opened by tearing along line A-A in figure 1 and the catheter fully extruded from the bag.

Figure 3 is a section across B-B in figure 1.

Referring now to Figure 1 there is shown a catheter 4 with rounded distal tip 6, drainage eye 8 and enlarged proximal portion 5 inside a container 2 made from two layers 10 and 11 of flexible plastic film such as polyethylene or PVC sealed on all edges 1 and with an interrupted seal 9 where the aperture 3 in the seal 9 is of dimensions suitable to permit free passage of the catheter shaft but will engage with the larger, proximal portion 5 of the catheter.

The sealed flexible container 2 can be conveniently opened by tearing along the line A-A from the pre-cut point 7 to expose the catheter tip 6 ready for insertion into the patients urethra. This assembly of catheter and flexible container may be further packaged in a second sealed pouch (not shown) and sterilised if required by suitable means such as irradiation from a cobalt 90 source to provide an assembly as shown in Figure 1 which is sterile on both the outside and the inside of the flexible container.

Referring now to Figure 2, there is shown a flexible container 2 from which the catheter 4 has been extruded through the aperture 3 in the seal 9 such that the proximal end 5 of the catheter 4 is lodged within the aperture 3 to form a mechanical seal against leakage of urine from the flexible container 2.

Referring now to Figure 3, there is shown a cross section of the catheter 4 with its drainage lumen 12 positioned in the aperture 3 within the interrupted weld 9 which seals the upper layer of plastic film 10 to the lower layer of plastic film 11.

CLAIMS

- 1 A catheter made from plastics material and having a smooth, substantially parallel, shaft portion with a distal end comprising a rounded, closed tip portion, at least one drainage aperture piercing the wall of the shaft portion to the central drainage lumen of the catheter and a proximal end comprising a gradually flared portion integral with the shaft of the catheter and open to permit the flow of urine, the said catheter is enclosed within an elongated, flexible, plastic container comprising flat, flexible, imperforate plastic sheet material sealed along all edges save for a preformed aperture at one end of the said container sufficiently large to permit the shaft of the catheter to pass through, but small enough to engage with the flared funnel portion at the proximal end of the catheter and form a seal against leakage of urine collected in the container, the said catheter being removably retained within the confines of the preformed aperture until the said aperture is distorted or ruptured.
- 2 A catheter and urine collection device assembly as described in claim 1 wherein the surface of catheter shaft contains indentations such as grooves or a frosting effect to reduce surface friction.
- 3 A catheter and urine collection device assembly as described in claims 1-2 above wherein the container is sealed distal to the preformed aperture such that the distal portion of the bag must be removed to expose the preformed aperture prior to use.
- 4 A catheter and urine collection device assembly as described in claims 1-3 wherein the assembly is rendered sterile by such means as exposure to irradiation or ethylene oxide gas.

5 A catheter and urine collection device assembly as described in claims 1-3 wherein the assembly is contained within a second, sealed pouch and rendered sterile by such means as exposure to irradiation or ethylene oxide gas.

6 A catheter and urine collection device assembly as in claims 1-5 wherein the catheter is identical in all respects other than at the proximal end where the flared portion is of smooth surface and round cross section for at least a part of its length.

7 A catheter and urine collection device assembly as in claims 1-6 wherein the flared portion at the proximal end of the catheter is in the form of a separate, moulded component added to the catheter shaft during or after manufacture.

8 A catheter and urine collection device assembly as described in claims 1-7 wherein the catheter is prelubricated.

9 A catheter and urine collection bag assembly as described in claims 1-7 wherein a separate container of a lubricious substance is included within the urine collection device assembly.

10 A catheter and urine collection device assembly as described in claim 9 wherein the container of lubricious substance is a sealed sachet in which a portion or portions of the seal are weakened to permit the sachet to burst under hand pressure.

Patents Act 1977
Examiner's report to the Comptroller under Section 17
(The Search report)

Application number
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Relevant Technical Fields

- (i) UK Cl (Ed.N) A5R (RCED, RCEX, RGEX, RGH)
(ii) Int Cl (Ed.6) A61F 5/44; A61M 1/00, 25/00

Search Examiner
L V THOMAS

Date of completion of Search
6 MARCH 1995

Databases (see below)

- (i) UK Patent Office collections of GB, EP, WO and US patent specifications.

Documents considered relevant following a search in respect of Claims :-
1-10

(ii)

Categories of documents

- X:** Document indicating lack of novelty or of inventive step. **P:** Document published on or after the declared priority date but before the filing date of the present application.
Y: Document indicating lack of inventive step if combined with one or more other documents of the same category. **E:** Patent document published on or after, but with priority date earlier than, the filing date of the present application.
A: Document indicating technological background and/or state of the art. **&:** Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
Y	GB 2033231 A	(ILLINOIS TOOL WORKS) see page 2 lines 27-66 and page 3 lines 13-24	3,9
X,Y	GB 2031735 A	(REHABILITATION INST) see Figures 1-3, page 1 line 20 to page 2, line 14 and page 2 lines 49-78 (= US 4246909)	X: 1,4,6 Y: 3,9
X,Y	US 5147341	(STARKE ET AL) see column 1 lines 46-58 and column 2 line 43 to column 3 line 7	X: 1,4,6,7 Y: 3,9
X,Y	US 4204527	(WU ET AL) see Figures 1-3, column 2 line 66 to column 3 line 18, column 3 lines 32-54 and particularly column 5 lines 9-13	X: 1,4,6 Y: 3,9

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

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